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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-41

March 23, 2000

Mrs. Lillie I. Metcalf, President
Alex Seafood Company, Inc.
7710 Palmo Fish Camp Road
St. Augustine, FL 32092

Dear Mrs. Metcalf:

We inspected your firm, located at Hwy 98 West, Perry, FL on September 29, 1999 and found serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to the attention of your manager, Ms. A. Faye Hutcheson, cause the fresh crabmeat produced in this facility to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (Act). You can find this Act and the seafood HACCP regulations through links in the FDA's home page at www.fda.gov.

The deviations were as follows:

You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for fresh crabmeat does not list the critical control point(s) of cooking and finished product storage to control the food safety hazards of pathogen survival, growth and toxin formation.

You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for fresh crabmeat does not list the monitoring procedures or frequencies at the picking and packing critical control point to control the pathogen growth and toxin formation hazards. In addition to monitoring the time a marked basket of cooked crabs is removed from the cooler to the time the last pound of crabmeat from the marked basket is placed in the cooler, your plan must provide for the monitoring of maximum product temperature achieved during picking or ambient temperature during picking.

You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm maintained sanitation control records that are not adequate because they did not document the prevention of cross contamination or control of employee health conditions.

You must retain records at the processing facility for at least 1 year after the date they were prepared in the case of refrigerated products, to comply with 21 CFR 123.9(b)(1). However HACCP forms such as the Daily Picking & Packing Log were only retained at the processing facility for two days.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a copy of your HACCP plan, monitoring records and sanitation control records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Kendall W. Hester, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Hester at (407) 475-4730.

Sincerely,



Marie A. Urban
Acting Director, Florida District